

Department of Health and Human Services  
National Institutes of Health  
National Institute of Allergy and Infectious Diseases

The National Institute of Allergy and Infectious Diseases (NIAID) conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. For more than 50 years, NIAID research has led to new therapies, vaccines, diagnostic tests, and other technologies that have improved the health of millions of people in the United States and around the world.

In the NIAID Dale and Betty Bumpers Vaccine Research Center (VRC), the Vaccine Production Program (VPP) laboratory has an opening for a staff scientist. The VPP develops and produces candidate vaccines suitable for evaluation, in small and large clinical trials, to test safety, immunogenicity, and efficacy in blocking infection.

The incumbent will serve as the principal regulatory expert for the VPP and VRC, which entails managing the regulatory process to meet FDA requirements and to gain FDA approval of VRC vaccines for clinical trials. The incumbent will serve as the responsible head for chemistry, manufacturing, and controls (CMC) of all investigational new drug (IND) applications for vaccines and related products and oversee the planning, preparation, and review of IND materials to ensure compliance with FDA guidelines and the Code of Federal Regulations (CFR).

The incumbent will develop regulatory strategies appropriate for manufacturing candidate products for Phase I, II, and III trials, e.g., planning, reviewing, and overseeing manufacturing methods, toxicology protocols, and preclinical packages. The incumbent will provide expertise for testing and characterizing strategies for cell substrates, vaccine constructs, and vaccine formulation. As a recognized authority and team leader, the incumbent will analyze unique problems involved with regulatory requirements and related scientific analysis. The incumbent will be responsible for assembling all CMC IND packages for integration and submission to regulatory authorities by other intramural or extramural agencies.

The incumbent will serve as the primary liaison on regulatory matters with several different groups: with intramural (DAIDS and RCHSPB) and extramural collaborators and program officials at NIAID on joint vaccine development projects, as well as with foreign governments and international health organizations for the clinical use of vaccines within their jurisdictions and to resolve issues related to foreign regulations and requirements.

The incumbent must communicate regulatory strategy effectively with high-level scientists, physicians, managers, and administrators, as well as with consultants, contractors, and other interested parties. The incumbent must work effectively with VRC and NIAID staff and participate in an overall team approach involving high-visibility projects within VRC, NIAID, NIH, and the scientific community.

The incumbent will serve under the general supervision of the director of the VPP, who provides broad administrative and scientific direction. Advice, information, and recommendations developed by the incumbent form the basis for decisions by the director.

**Requirements:**

Ph.D. in the biological sciences with a minimum of fifteen years' scientific experience, which includes a minimum of ten years' regulatory experience in either vaccines or therapeutic proteins, is required.

Previous regulatory experience in CMC for clinical or commercial products with prior leadership in the submission of INDs and BLAs is required. The candidate must have expert knowledge of regulatory issues and procedures involved in vaccine manufacture, testing, characterization, and IND preparation and processing, including detailed knowledge of FDA regulatory requirements, vaccine manufacturing methods, and preclinical testing strategies. Comprehensive knowledge of the medical sciences related to vaccines (e.g., immunology) as related to preclinical and clinical vaccine development is beneficial.

For additional information about the position, contact Dr. Richard Schwartz, chief of VPP, at 301-594-8485 or [schwartzri@mail.nih.gov](mailto:schwartzri@mail.nih.gov).

To apply, submit a curriculum vitae, a bibliography, and names of three references to Dr. Schwartz via e-mail at [schwartzri@mail.nih.gov](mailto:schwartzri@mail.nih.gov) or mail at National Institute of Allergy and Infectious Diseases, Dale and Betty Bumpers Vaccine Research Center, Office of the Chief, Attn: Dr. Richard Schwartz, Building 40, Room 5502, Convent Drive, Bethesda, MD 20892-3015. E-mail is preferred.

For further information about NIAID and other available career opportunities, please visit us on the Web at [www.niaid.nih.gov/careers/ssb](http://www.niaid.nih.gov/careers/ssb).

HHS, NIH, and NIAID are proud to be Equal Opportunity Employers.